

Utfärdare/Issuer Louise Lindblad	Ref nr/Dok nr/Ref no/Doc no	Utgåva /Edition 1
Avser/Regarding GammaPlan®	Directory	

**Section 4- 510(k) Summary** *K051022*

As Required by 21 CFR 807.87(k)510 (k) Summary

**1. Subscribers Name & Address**

Elekta Instrument AB  
Kungstensgatan 18, P:O Box 7593  
SE-103 93 Stockholm, Sweden  
Tel: (011) 46 8 587 254 00  
Fax: (011) 46 8 587 255 00  
Contact Person for this submission: Ms Louise Lindblad  
Official Correspondent: Mr Peter Löwendahl

**2. Trade Name**

GammaPlan®

**3. Device Classification**

Common Name	Product Code	Class	Regulation Number
Radionuclide radiation therapy system	IWB	II	892.5750

**4. Regulatory History (Unmodified Predicate Device)**

Devices	510(k) #
Leksell GammaPlan®	K973441
Leksell GammaPlan® 4C with MultiView	K042269

**5. Other relevant submissions**

Devices	510(k) #
Leksell Gamma Knife® Target System, Model 24001	K984328

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**6. Device Description (for detailed description see Section "Device Description")**

GammaPlan® is a computer-based dose planning system specifically designed for use with the Gamma Knife®. Gamma Plan® is intended to be used for planning the dosimetry of treatments, in stereotactic radiosurgery and stereotactic radiotherapy.

**7. Intended Use**

GammaPlan® is a computer-based system designed for Gamma Knife® treatment planning.

**8 Substantial Equivalence**

The functionality for the GammaPlan® is equivalent to its predicate device Leksell GammaPlan® (K973441) and Leksell GammaPlan® 4C with MultiView (K042269) in safety and effectiveness. The fundamental technical characteristics are similar to those of the predicate device.



JUN 1 - 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Peter Löwendahl  
Manager Quality & Regulatory Affairs  
Elekta Instrument AB  
Kunsgstensgatan 18, P.O. Box 7593  
Stockholm, SE-10393  
SWEDEN

Re: K051022  
Trade/Device Name: GammaPlan®  
Regulation Number: 21 CFR 892.5750  
Regulation Name: Radionuclide radiation  
therapy system  
Regulatory Class: II  
Product Code: IWB and MUJ  
Dated: April 13, 2005  
Received: April 22, 2005

Dear Mr. Löwendahl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**ELEKTA INSTRUMENT AB**

Dokumentnamn/Name of document

Traditional 510(k)

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**Section 7- Indications for Use Statement**

510(k) Number

To be defined

K051022

Device Name

GammaPlan®

Indications for Use

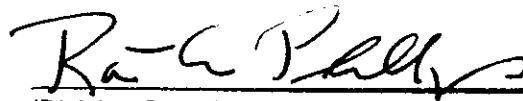
GammaPlan® is a computer-based system designed for Gamma Knife® treatment planning.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices510(k) Number   K051022